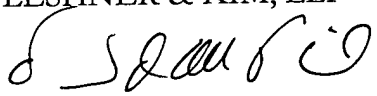
REMARKS

Claims 1-76 are pending. Claims 1-73 have been amended to reflect the accurate count of Claims 1-76. Previously in filing our patent application, Claims 1-73 were misnumbered and now this Preliminary Amendment reflects an accurate count of claims. Prompt examination and allowance in due course are respectfully solicited.

Respectfully submitted,
FLESHNER & KIM, LLP



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Amended Claims With Mark-ups to Show Changes Made

23. [22.] (Amended) The method according to claim 2, wherein said residual solvent content is less than about 10%.

24. [23.] (Amended) The method according to claim 2, wherein said residual solvent content is less than about 3%.

25. [24.] (Amended) The method according to claim 2, wherein said residual solvent content is less than about 2%.

26. [25.] (Amended) The method according to claim 2, wherein said residual solvent content is less than about 1%.

27. [26.] (Amended) The method according to claim 2, wherein said residual solvent content is less than about 0.5%.

28. [27.] (Amended) The method according to claim 2, wherein said residual solvent content is less than about 0.08%.

29. [28.] (Amended) The method according to claim 1, 2 or 3, wherein at least one sensitizer is added to said biological material prior to said step of irradiating said biological material.

30. [29.] (Amended) The method according to claim 1, 2 or 3, wherein said biological material contains at least one prion as a biological contaminant or pathogen.

31. [30.] (Amended) The method according to claim 1, 2 or 3, wherein said biological material contains at least one biological contaminant or pathogen selected from the group consisting of viruses, bacteria and fungi.

32. [29.] (Amended) The method according to claim 1, 2 or 3, wherein at least one additional stabilizer is added to said biological material prior to said step of irradiating said biological material.

33. [30.] (Amended) The method according to claim 28 [27], wherein said at least one additional stabilizer is an antioxidant.

34. [31.] (Amended) The method according to claim 28 [27], wherein said at least one additional stabilizer is a free radical scavenger.

35. [32.] (Amended) The method according to claim 28 [27], wherein said at least one additional stabilizer is a combination stabilizer.

36. [33.] (Amended) The method according to claim 28 [27], wherein said at least one additional stabilizer is a ligand.

37. [34.] (Amended) The method according to claim 36 [33], wherein said ligand is heparin.

38. [35.] (Amended) The method according to claim 28 [27], wherein said at least one additional stabilizer reduces damage due to reactive oxygen species.

39. [36.] (Amended) The method according to claim 28 [27], wherein said at least one additional stabilizer is selected from the group consisting of: ascorbic acid or

a salt or ester thereof; glutathione; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate and mixtures of two or more thereof.

40. [37.] (Amended) The method according to claim 39 [36], wherein said mixtures of two or more additional stabilizers are selected from the group consisting of: mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; and mixtures of uric acid, or a salt or ester thereof; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

41. [38.] (Amended) The method according to claim 1, 2 or 3, wherein said at least one dipeptide stabilizer is selected from the group consisting of glycyl-glycine (Gly-Gly), carnosine and anserine.

42. [39.] (Amended) The method according to claim 1, 2 or 3, wherein said radiation is corpuscular radiation or electromagnetic radiation, or a mixture thereof.

43. [40.] (Amended) The method according to claim 42 [39], wherein said electromagnetic radiation is selected from the group consisting of radio waves,

microwaves, visible and invisible light, ultraviolet light, x-ray radiation, gamma radiation and combinations thereof.

44. [41.] (Amended) The method according to claim 1, 2 or 3, wherein said radiation is gamma radiation.

45. [42.] (Amended) The method according to claim 1, 2 or 3, wherein said radiation is e-beam radiation.

46. [43.] (Amended) The method according to claim 1, 2 or 3, wherein said radiation is visible light.

47. [44.] (Amended) The method according to claim 1, 2 or 3, wherein said radiation is ultraviolet light.

48. [45.] (Amended) The method according to claim 1, 2 or 3, wherein said radiation is x-ray radiation.

49. [46.] (Amended) The method according to claim 1, 2 or 3, wherein said radiation is polychromatic visible light.

50. [47.] (Amended) The method according to claim 1, 2 or 3, wherein said radiation is infrared.

51. [48.] (Amended) The method according to claim 1, 2 or 3, wherein said radiation is a combination of one or more wavelengths of visible and ultraviolet light.

52. [49.] (Amended) The method according to claim 1, 2 or 3, wherein said irradiation is conducted at ambient temperature.

53. [50.] (Amended) The method according to claim 1, 2 or 3, wherein said irradiation is conducted at a temperature below ambient temperature.

54. [51.] (Amended) The method according to claim 1, 2 or 3, wherein said irradiation is conducted below the freezing point of said biological material.

55. [52.] (Amended) The method according to claim 1, 2 or 3, wherein said irradiation is conducted below the eutectic point of said biological material.

56. [53.] (Amended) The method according to claim 1, 2 or 3, wherein said irradiation is conducted at a temperature above ambient temperature.

57. [54.] (Amended) A composition comprising at least one biological material and at least one dipeptide stabilizer in an amount effective to preserve said biological material for its intended use following sterilization with radiation.

58. [55.] (Amended) The composition according to claim 57 [54], further comprising at least one additional stabilizer selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; diosmin; silymarin; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; a mixture of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; a mixture of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; a mixture of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-

tetramethylchroman-2-carboxylic acid; and a mixture of uric acid, or a salt or ester thereof and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, said at least one additional stabilizer is present in an amount effective to preserve said biological material for its intended use following sterilization with radiation.

59. [56.] (Amended) The composition of claim 57 [54], wherein the residual solvent content is sufficiently low to preserve said biological material, during sterilization by irradiation, for its intended use following sterilization with radiation.

60. [57.] (Amended) The composition of claim 59 [56], wherein said residual solvent content is less than about 15%.

61. [58.] (Amended) The composition of claim 59 [56], wherein said residual solvent content is less than about 10%.

62. [59.] (Amended) The composition of claim 59 [56], wherein said residual solvent content is less than about 5%.

63. [60.] (Amended) The composition of claim 59 [56], wherein said residual solvent content is less than about 2%.

64. [61.] (Amended) The composition of claim 59 [56], wherein said residual solvent content is less than about 1%.

65. [62.] (Amended) The composition of claim 59 [56], wherein said residual solvent content is less than about 0.5%.

66. [63.] (Amended) The composition of claim 59 [56], wherein said residual solvent content is less than about 0.08%.

67. [64.] (Amended) The composition of claim 59 [56], wherein said biological material is glassy or vitrified.

68. [65.] (Amended) The composition of claim 57 [54], wherein said biological material is selected from the group consisting of monoclonal immunoglobulins, polyclonal immunoglobulins, glycosidases, sulfatases, urokinase and Factor VIII.

69. [66.] (Amended) The composition of claim 59 [56], wherein the concentration of said biological material is at least about 0.5%.

70. [67.] (Amended) The composition of claim 59 [56], wherein the concentration of said biological material is at least about 1%.

71. [68.] (Amended) The composition of claim 59 [56], wherein the concentration of said biological material is at least about 5%.

72. [69.] (Amended) The composition of claim 59 [56], wherein the concentration of said biological material is at least about 10%.

73. [70.] (Amended) The composition of claim 59 [56], wherein the concentration of said biological material is at least about 15%.

74. [71.] (Amended) The composition of claim 59 [56], wherein the concentration of said biological material is at least about 20%.

75. [72.] (Amended) The composition of claim 59 [56], wherein the concentration of said biological material is at least about 25%.

76. [73.] (Amended) The composition of claim 59 [56], wherein the concentration of said biological material is at least about 50%.